SMARTABLATE™ SYSTEM

Irrigation Pump User Manual

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CE 0366

Manufactured by
Stockert GmbH

Distributed by
Biosense Webster
a Johnson & Johnson company

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Preface

The SmartAblate™ Irrigation Pump is a peristaltic pump designed to work in conjunction with the SmartAblate™ RF Generator to deliver irrigation solution at specified flow rates to irrigated catheters (such as the Biosense Webster Celsius® ThermoCool® Catheters and NaviStar® ThermoCool® Catheters) for cooling purposes. The pump is used with the SmartAblate™ Irrigation Tubing Set that conducts the irrigation solution from an external source to the compatible irrigated catheters.

The SmartAblate™ Irrigation Pump was designed to allow simple, intuitive, and user-friendly operation. When connected to the SmartAblate™ RF Generator by the supplied interface cable, the pump can be controlled directly from the user interface of the generator. Simultaneously, the pump transfers status information regarding solution flow rates back to the SmartAblate™ RF Generator to allow safe operation. If an error occurs in either of these devices, the necessary notification and recovery steps are initiated simultaneously in both devices.

The pump can be operated directly from the pump user interface when it is not connected to the SmartAblate™ RF Generator.

Use of the SmartAblate™ Irrigation Pump requires familiarity with the device and its operation. The user should read this manual, which describes how to operate the SmartAblate™ Irrigation Pump, and should attend a presentation on the operation and configuration of the pump provided by Biosense Webster. The user should also become familiar with the SmartAblate™ RF Generator and all accessories and read their instructions for use before using the generator or accessories.

For more information on training options, please contact Biosense Webster.

We will gladly answer any questions that you may have.

Yours truly,

STOCKERT GmbH

1 Indications

The SmartAblate™ Irrigation Pump is a peristaltic pump designed to work in conjunction with the SmartAblate™ RF Generator to deliver irrigation solution at specified flow rates to irrigated catheters (such as the Biosense Webster Celsius® ThermoCool® Catheters and NaviStar® ThermoCool® Catheters) for cooling purposes. The pump is used with the SmartAblate™ Irrigation Tubing Set that conducts the irrigation solution from an external source to the compatible irrigated catheters.

2 Warnings

1. Before setting up the SmartAblate™ Irrigation Pump for the first time, carefully read this user manual. Pay special attention to the instructions in Chapter 3, Pump Setup. Also read the user manuals for the SmartAblate™ RF Generator and the accessories and familiarize yourself with their use.

2. Always verify that the pump's visual and acoustic alarms are working before using the pump (see Section 5.1, Turning the Pump On and Off).

3. When the pump has been turned off, power continues to be supplied to the pump through the mains cable. To completely cut off power to the pump, disconnect the mains cable from the pump. To allow easy disconnection in the event of severe power failure, make sure that the pump is located where there is easy access to the mains cable.

4. After turning on the pump, always wait until the automatic self test has been successfully completed before starting the first steps of the procedure on the patient (for example, before anesthesia or before creating percutaneous access). Doing this helps to detect problems with the device before the patient is in a phase of the intervention in which interruption could lead to an increased risk to the patient's health.

5. Use only accessories that have been provided by or recommended by the pump's manufacturer (see Chapter 4, Accessories). The use of other accessories can have a negative effect on the technical specifications. Do not modify accessories. Visually inspect all accessories on a regular basis. Make sure that the connected cables are not damaged. When using sterile accessories, be sure to maintain the sterility of those accessories.

6. Inspect the pump for damage before each use (see Section 7.5, Maintenance).

7. Special safety measures with regard to electromagnetic compatibility (EMC) must be taken with electrical medical devices. Portable and mobile communication devices may cause harmful interference to the functioning of the pump. Do not use portable or mobile communication devices in the vicinity of the SmartAblate™ Irrigation Pump.

8. Radio interference and electromagnetic fields can trigger false alarms and malfunctions in electrical units such as the SmartAblate™ Irrigation Pump. Furthermore, use of electrical units such as this pump can occasionally result in wrong values on ECG monitors that are not operated under optimal conditions. Although the pump is designed to avoid such interference, when the pump is used with electromagnetic navigation systems and ECG monitors, verify correct operation of the connected devices before use on a patient. If interference occurs, move the pump to another location.

9. If error messages repeatedly appear, stop using the pump and contact Customer Support.

10. To avoid damage to the pump and its accessories, use only appropriate cleaning agents (see Section 3.12, Cleaning and Disinfecting the Pump).

11. There are no parts in the SmartAblate™ Irrigation Pump that may be serviced by the user. (Exception: The fuses may be replaced per Section 3.6, Fuses.)

12. The pump enclosure may be opened only by persons authorized by the manufacturer. When the pump enclosure is open, parts that have high voltage or are very hot are accessible and can cause injury. If the pump enclosure is opened by an unauthorized person, any claims on the warranty are void. No modification of the pump is permitted.

13. The SmartAblate™ Irrigation Pump was calibrated by the manufacturer. Changing pump settings other than those described in Chapter 5, Pump Operation, will result in improper functioning and will void the warranty.

14. If fluid penetrates into the pump, stop using the pump and contact Customer Support.

15. Use the SmartAblate™ Irrigation Pump only in combination with the SmartAblate™ Irrigation Tubing Set. If unsuitable tubing is used, the pump will not function properly and improper irrigation will result.

16. The sterile SmartAblate™ Irrigation Tubing Set is intended for one-time patient use. To avoid biological contamination and ensure proper functioning, do not reuse or resterilize the tubing set.

17. The SmartAblate™ Irrigation Pump monitors the flow of irrigation solution. If there is a problem with the solution flow, the pump stops the flow and issues an alarm. Correct alarm situations and restart the flow as quickly as possible.

18. The hospital staff is responsible for ensuring that the pump is functioning properly and that the solutions and irrigated catheters that are used in the overall irrigation process are compatible with each other. The SmartAblate™ Irrigation Pump and the SmartAblate™ Irrigation Tubing Set are intended for use with a standard irrigation solution such as a normal isotonic saline solution. The precision of the flow rate stated in the technical data may not be maintained if incompatible fluids and/or incompatible irrigated catheters are used.

19. The SmartAblate™ Irrigation Pump may be operated in the immediate vicinity of the SmartAblate™ RF Generator. However, do not operate the pump in the immediate vicinity of devices that are not approved for electromagnetic compatibility (EMC) with the pump. If such operation is unavoidable, regularly monitor the pump to ensure proper functioning.

20. Do not connect the SmartAblate™ Irrigation Pump to other infusion systems, including gravity intravenous (IV) infusion systems.

21. To prevent explosions, do not use the pump near explosive anesthetics.

22. To prevent electric shock and fires, do not expose the pump to excessive humidity.

23. To avoid the risk of electric shock, connect the pump to a 3-prong mains outlet that meets the specifications in Section 7.1, Specifications.

24. Parts such as the intravenous (IV) pole clamp, the rotating pump head, and the door that covers the pump head are designed for safe operation but must be used with caution.

25. The SmartAblate™ Irrigation Pump is intended for use with irrigated catheters. Monitor the irrigation flow rate to avoid hazards caused by insufficient irrigation flow. Monitoring the flow rate on the pump display alone is not sufficient because the flow rate is calculated from the pump motor speed. If the pump fails to rotate at the speed set by the user, the pump issues an alarm. However, because it is possible for a situation to arise during which the motor head is rotating but there is no flow, it is important to repeatedly monitor the approximate flow rate by observing the drip speed in the drip chamber. The drip chamber should be half to three-quarters filled to ensure no bubbles enter the tubing and provide visibility of the drip speed. The hospital staff is responsible for determining and monitoring the flow rate to avoid insufficient flow of the irrigation solution. The hospital staff is responsible for monitoring the total amount of solution delivered to the patient to avoid an excessive loading of the irrigation solution in the patient. For recommended flow rates, refer to the catheter's instructions for use.

26. The person who connects the devices and accessories to each other or who uses the devices and accessories is responsible and liable for installation and operation that complies with IEC/EN 60601-1-1.

27. All system components must comply with all applicable requirements and standards and must be labeled pursuant to these standards.

28. If there are any concerns regarding the use of a component, contact the distributor of the component to obtain further information.

29. The pump, the generator, and all accessories connected to the pump or generator, when located within the patient area, must comply with IEC/EN 60601-1 and its sub-standards.

30. If several devices are connected to each other, they should be as safe, both individually and together, as specified in IEC/EN 60601-1 and its sub-standards and IEC/EN 60601-1-2.

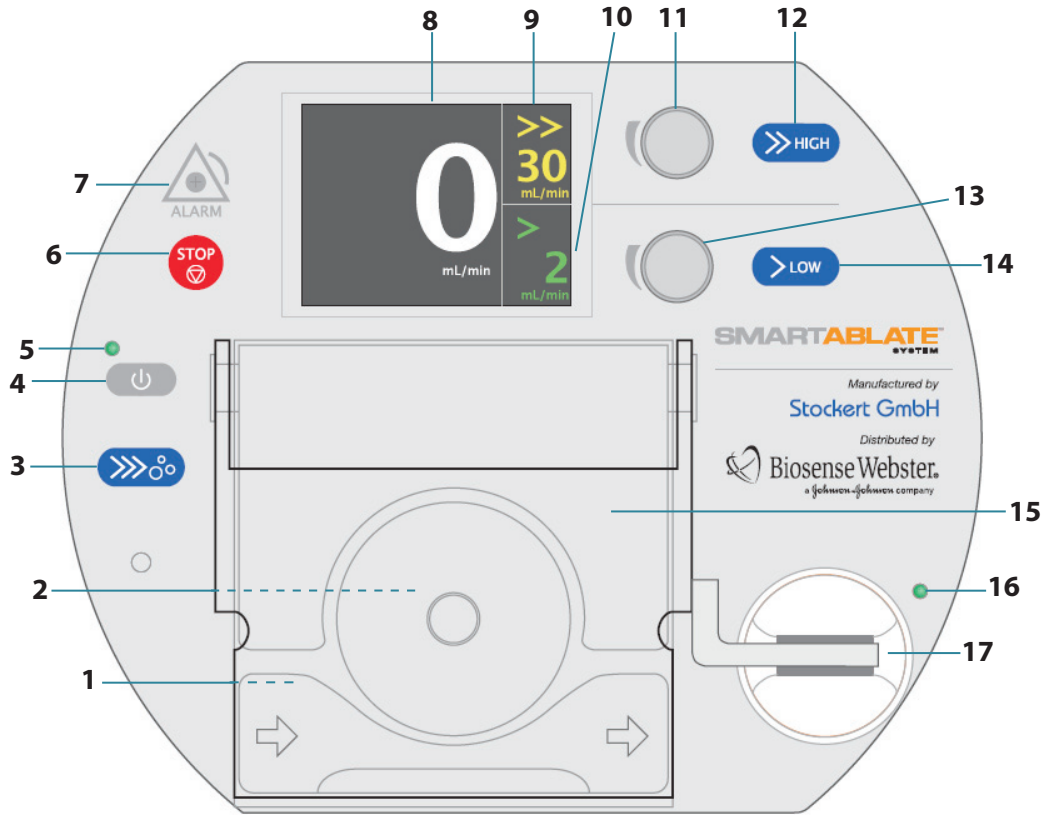
31. Do not put any labels or stickers on the front of the pump that will obscure the buttons or indicator lights.

32. The pump should be used only when the use of irrigation solution is appropriate relative to the medical condition of the patient. If it is not known what influence irrigation solution might have on a patient, consult with appropriate medical professionals before using this device.

33. When the pump is used alone for an ablation procedure, without being controlled by an RF generator, high flow of the irrigation solution should be started before the RF energy is turned on to allow the desired flow rate to be reached at the tip of the catheter. High flow should be continued for a few seconds after the RF energy is turned off in order to avoid thrombus formation on the ablation electrode.

3 Pump Setup

3.1 Controls on the Front of the Pump

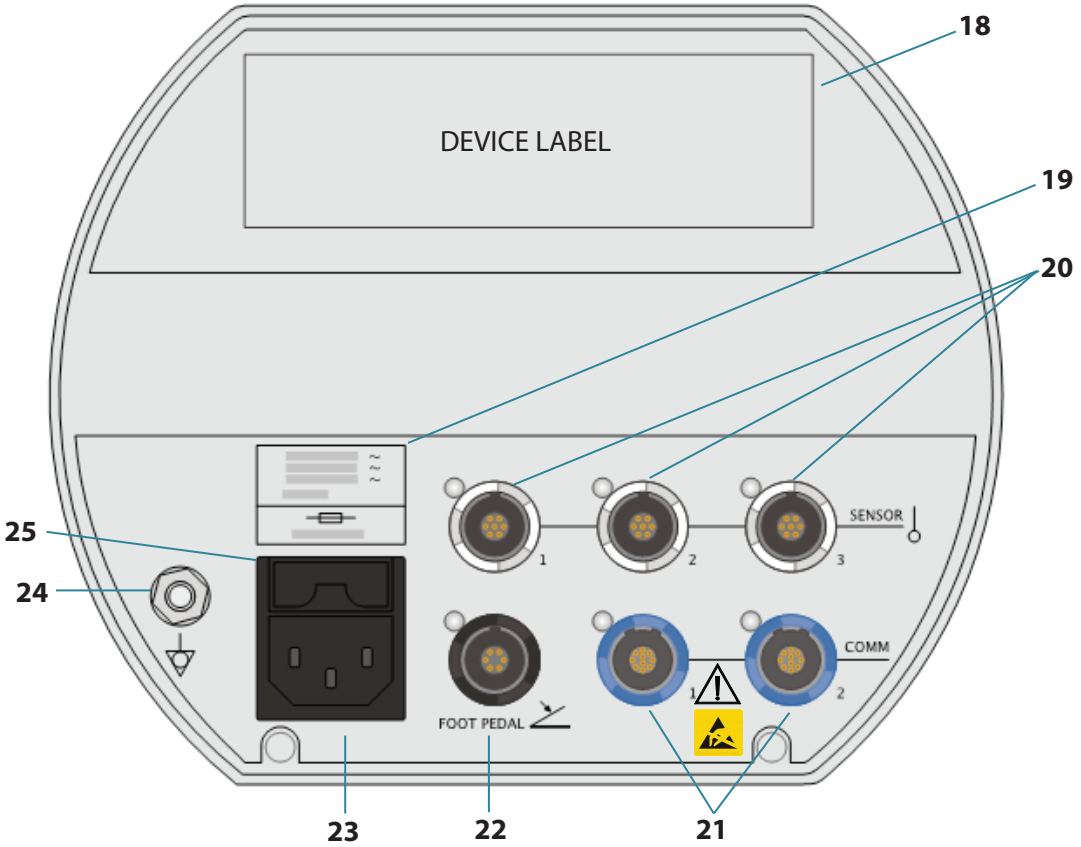


Item	Description
1	Pump head pressure plate
2	Pump head
3	**Flush** button
4	**Stand-by** button
5	**Stand-by** indicator
6	**Stop** button
7	**Alarm** indicator
8	Active flow rate
9	Selected high (ablation) flow rate
10	Selected low (standby) flow rate
11	**High (Ablation) Flow** knob
12	**High (Ablation) Flow** button
13	**Low (Standby) Flow** knob
14	**Low (Standby) Flow** button

Item	Description
15	Pump door*
16	Air bubble indicator
17	Air bubble sensor

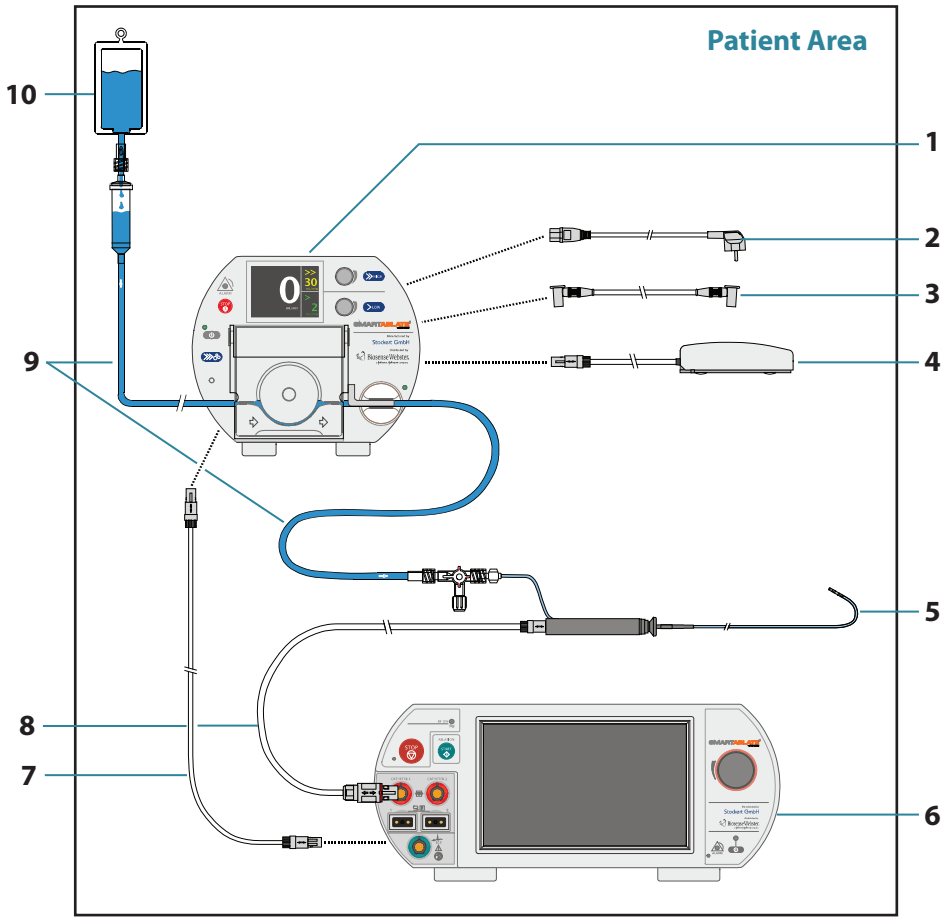
*The transparent pump door allows viewing of the tubing and the pump head rotation.

3.2 Controls on the Back of the Pump



Item	Description
18	Device label
19	Mains rating label
20	Sensor receptacles, and indicators (not functional)
21	Communication receptacles for RF generator, and indicators
22	Receptacle for foot pedal, and indicator
23	Mains socket
24	Potential equalization port
25	Fuse cover

3.3 Diagram of the Pump with the SmartAblate™ RF Generator and Accessories



Item	Description
1	SmartAblate™ Irrigation Pump
2	Mains cable*
3	Grounding cable*
4	Foot pedal*
5	Catheter
6	SmartAblate™ RF Generator
7	SmartAblate™ Irrigation Pump connection cable*
8	Catheter connection cable
9	SmartAblate™ Irrigation Tubing Set*
10	Fluid bag

*See Chapter 4, Accessories.

3.4 Pump Location

The SmartAblate™ Irrigation Pump can be located in any of the following locations:

- On a clean, flat, stable surface
- On a Carto® 3 System cart
- On an intravenous (IV) pole (see the instructions for use provided with the pole clamp)

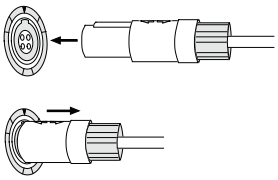
3.5 Mains Connection

The SmartAblate™ Irrigation Pump automatically adjusts for the necessary mains voltage and frequency. To avoid the risk of electric shock, connect the pump to a 3-prong mains outlet that meets the specifications in Section 7.1, Specifications. Use only the mains cable supplied by the manufacturer or distributor for the country where the pump is being used.

3.6 Fuses

Externally accessible fuses for the SmartAblate™ Irrigation Pump are located under the fuse cover (see Item 25 in Section 3.2, Controls on the Back of the Pump). Use only fuses approved by the manufacturer.

3.7 Circular Plug Connections



The circular plugs on the SmartAblate™ System cables and the SmartAblate™ System foot pedal cable are color coded to ensure simple and accurate connection to the receptacles of the same color on the back of the SmartAblate™ Irrigation Pump (see Items 21 and 22 in Section 3.2, Controls on the Back of the Pump). The indicator for the foot pedal receptacle and the indicator for the COMM 1 receptacle are orange to indicate that the receptacles are functional and are ready for connection. To connect a circular plug to the pump, align the arrow on the plug with the mark on the receptacle and push in without unnecessary force until a click indicates that the connector is locked in the receptacle. If the plug does not fit in the receptacle, verify that the color coding matches and that the number of pins in the plug is appropriate for the receptacle. To remove a circular plug, gently pull back the sleeve on the plug and pull the plug out of the receptacle.

3.8 Potential Equalization

To avoid differences in potential between the pump and other devices with power operation, the SmartAblate™ Irrigation Pump must be connected to a grounding line (as specified in IEC/EN 60601-1). Connect one end of the green and yellow potential equalization cable provided with the pump to the grounding connection on the back of the pump (see Item 24 in Section 3.2, Controls on the Back of the Pump). Connect the other end to the room's central grounding line. To avoid radiation interference (noise) in the ECG signal, always use the same grounding line for connection of all devices involved (electrocardiograph, Carto® System, generator).

3.9 Foot Pedal Connection

See Section 3.7, Circular Plug Connections.

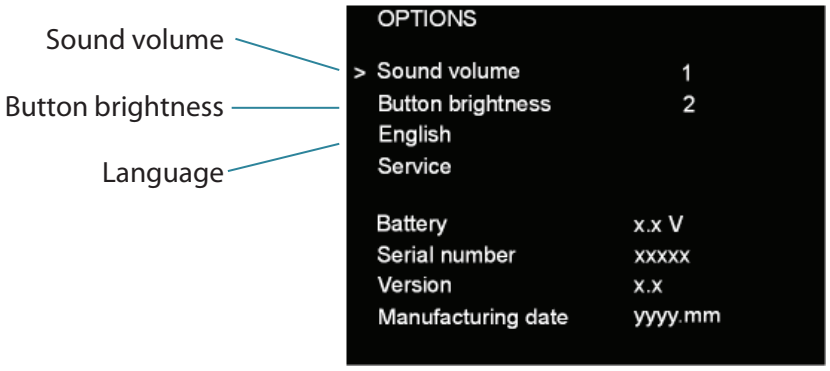
3.10 Connection to the RF Generator

Turn on the RF generator and the SmartAblate™ Irrigation Pump (see Section 5.1, Turning the Pump On and Off).

Plug the connection cable from the RF generator into the COMM 1 receptacle on the back of the pump as described in Section 3.7, Circular Plug Connections. For additional instructions, see Section 5.8, Communication with the SmartAblate™ RF Generator.

3.11 Adjusting the Volume, Brightness, and Language

Options Screen



Turn off the pump and close the pump door.

Press and hold the **Low (Standby) Flow** button while you briefly press the **Stand-by** button. Release the **Low (Standby) Flow** button when the Options screen appears.

Turn the **High (Ablation) Flow** knob until > appears to the left of the setting that you want to change.

Then turn the **Low (Standby) Flow** knob to change the sound volume, button brightness, or language setting.

Press the **Stand-by** button to remove the information from the screen. The pump will turn off.

Note: The **Service** selection on the Options screen is for use by a service engineer certified by the manufacturer.

3.12 Cleaning and Disinfecting the Pump

WARNINGS

- The SmartAblate™ Irrigation Pump must be turned off and the mains cable must be disconnected from the pump before cleaning and disinfecting the pump.
- The SmartAblate™ Irrigation Pump, the mains cable, and the connection cable to the SmartAblate™ RF Generator must not be sterilized.

Use a dry microfiber cloth to clean the pump's screen. If damp cleaning is necessary, moisten a soft cotton or linen cloth with commercial grade glass cleaner that does not contain alcohol and wipe the screen. Do not spray the cleaner directly onto the screen.

Use a soft, damp, lint-free cloth to clean and disinfect the housing of the pump. Use only non-flammable and non-explosive substances. Water or soapy water is recommended for cleaning. Make sure that no liquid penetrates the inside of the pump.

The following disinfectants can be used for disinfecting the pump and its cables:

- Lysoformin® spezial
- Kodan®
- Meliseptol®
- Commercial disinfectants that do not contain ethyl alcohol

Caution: The following substances must not be used: acetone, benzene, acids of any kind (including acetic acid and citric acid), scouring agents, nitro dilutions and other organic solvents. Do not use any agent containing ethyl alcohol to clean the pump. Iodine or disinfectants containing dyes cause discoloration of the housing and should not be used. Perform disinfection by wiping, not spraying. Avoid condensation. If cleaning or disinfecting the pump with flammable or explosive substances cannot be avoided, make sure these substances have completely evaporated before the pump is turned on.

3.13 Protecting against Damage

In addition to being operated and maintained per the instructions in this user manual, the SmartAblate™ Irrigation Pump must also be protected against damage. This includes installing the pump in a safe location and protecting the pump against moisture, contamination, and contact with flammable or explosive substances.

Make sure that all cables to devices and accessories are arranged in a way that prevents tripping.

To transport the pump over long distances or to send the pump for service, use the original packaging. If the original packaging is not available, contact the manufacturer or distributor for a replacement.

3.14 Disposal

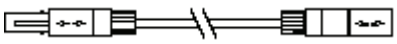
Inadequately treated electronic waste poses environmental and health risks. Follow local regulations for disposal of the SmartAblate™ Irrigation Pump and its electrical or electronic accessories. To ensure proper disposal, there is the option of contacting your Biosense Webster representative regarding return of the pump and its accessories.

4 Accessories

WARNING

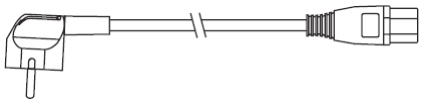
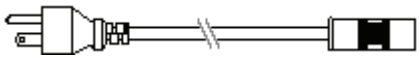
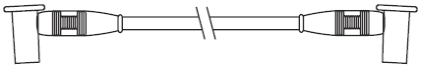
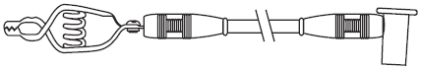
Use only the original accessories provided by or recommended by STOCKERT GmbH or Biosense Webster for the SmartAblate™ Irrigation Pump. If you use accessories not authorized by the manufacturer, the safety of the device and system is not guaranteed.

4.1 Foot Pedal

Item	Part #	
Foot Pedal, length of connection cable: 3 m		
Worldwide, except China	M490005	
China	M4900405	
Foot Pedal Extension Cable, length: 7 m (Redel-6 → Redel-6, black)	M490026	

4.2 SmartAblate™ Cables

Item	Part #	
Connection Cable from SmartAblate™ RF Generator to SmartAblate™ Irrigation Pump (Redel-10 → Redel-10, blue)		
length: 1 m	M490027	
length: 3 m	M490016	
length: 5 m	M490028	
length: 10 m	M490030	

Item	Part #	
Mains Cable, length: 3 m		
Australia	M4900601	
Brazil	M4900609	
China	M4900410	
EU	M4900108	
India / South Africa	M4900604	
Israel	M4900606	
Japan	M4900210	
Russia	M4900603	
Switzerland	M4900605	
Taiwan	M4900607	
UK / Singapore / Hong Kong	M4900602	
USA	M490024	
Grounding Cable, length: 3 m		
Worldwide, except Japan	M490014	
Japan	M490015	

4.3 Other Accessories

Item	Part #	
SmartAblate™ Irrigation Tubing Set	SAT001	
SmartAblate™ Irrigation Pump Intravenous (IV) Pole Clamp	M490037	—

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5 Pump Operation

Read this entire user manual before operating the SmartAblate™ Irrigation Pump.

The instructions in this chapter describe how to operate the SmartAblate™ Irrigation Pump using the pump's user interface. However, the pump can also be operated (including setting flow rates) using the SmartAblate™ RF Generator user interface (see Section 5.8, Communication with the SmartAblate™ RF Generator, and see the instructions in the user manual for the generator).

5.1 Turning the Pump On and Off

To turn the pump on, press the **Stand-by** button. The SmartAblate™ System logo appears on the screen, the **Alarm** indicator and the air bubble indicator lights turn on red (see Items 7 and 16 in Section 3.1, Controls on the Front of the Pump), and an audible tone is emitted briefly. If the logo does not disappear after 3 seconds, or if the indicators do not light, or if the tone cannot be heard, there could be a problem (see Section 6.4, Other Troubleshooting).

Note: If the generator is on when the pump is connected to the generator, the pump automatically turns on. If the generator is off when the pump is connected to the generator, the pump automatically turns on when the generator is turned on.

To turn the pump off, press the **Stand-by** button for at least 3 seconds.

Note: If the pump is connected to the generator and the generator is on, pressing the pump's **Stand-by** button puts the pump into sleep mode and the image at the right appears in the middle of the pump's screen. When the generator is turned off, the pump automatically turns off.

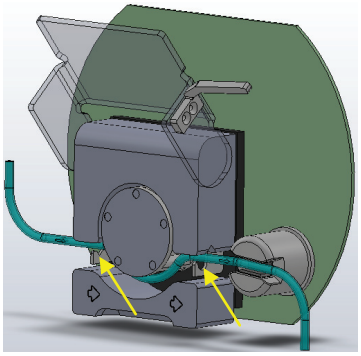
Note: If the voltage of the internal battery is low, the image at the right appears at the bottom of the pump's screen. You can continue to use the pump when this image is displayed but service will be required soon. Contact Customer Support.

5.2 Installing the SmartAblate™ Irrigation Tubing Set in the Pump

WARNINGS

- The tubing set is sterile and is intended for one-time patient use.
- The tubing set can be damaged if inserted incorrectly.
- Always use a new sterile tubing set obtained from its original packaging with each new procedure.

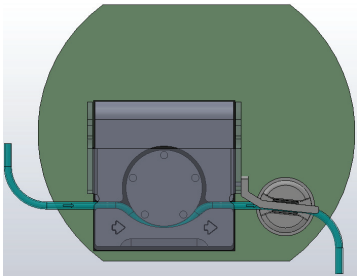
Install the SmartAblate™ Irrigation Tubing Set as described below. Also see the instructions for use provided with the tubing.



Open the pump door (see Item 15 in Section 3.1, Controls on the Front of the Pump).

Put the tubing between the pressure plate and the pump head (see Items 1 and 2 in Section 3.1). Make sure that the arrows on the tubing point in the same direction as the arrows on the pressure plate. Make sure that the tubing is in the grooves in the plates on each side of the pump head (see the arrows in the drawing at the left).

Gently stretch the tubing that extends from the right side of the pump head and insert it in the air bubble sensor (see Item 17 in Section 3.1).



Close the pump door. The pressure plate compresses the tubing to prevent fluid from flowing freely through the tubing set.

Take care not to pinch fingers when shutting the pump door.

After installing the tubing, flush the tubing as described in Section 5.3, Flushing to Eliminate Air in the Tubing and Catheter. The pump will not start fluid delivery if the tubing has not been flushed.

5.3 Flushing to Eliminate Air in the Tubing and Catheter

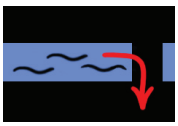
WARNINGS

- Irrigated catheters must be flushed before they are inserted in the patient.
- When flushing a catheter, the catheter must not be inside the patient. When flushing the SmartAblate™ Irrigation Tubing Set, either the catheter must be outside the patient or the 4-way stopcock on the tubing set must be turned so that the fluid is not routed to the catheter.

After the tubing has been installed, perform the following steps:

Press and hold the **Flush** button to remove all air bubbles from the tubing and the catheter. The pump head continues to rotate during flushing. The following images appear on the screen during flushing to indicate whether bubbles are detected in the bubble sensor area.

Bubbles Detected During Flushing


No Bubbles Detected During Flushing

Note: Flush for at least 5 additional seconds after the No Bubbles Detected During Flushing image appears and after there are no visible bubbles in the tubing. This ensures that all bubbles have been flushed from the catheter.

5.4 Starting the Irrigation Flow

WARNING
Low (standby) flow of the irrigation solution must be started before the catheter is inserted into the patient. If the catheter is introduced into the patient before irrigation is started, the holes in the catheter's tip electrode could become occluded due to thrombus formation.

Press the **Low (Standby) Flow** button to start the pump at the low (standby) flow rate.

Press the **High (Ablation) Flow** button to start the pump at the high (ablation) flow rate. During high (ablation) flow, the **High (Ablation) Flow** button blinks as a reminder that high (ablation) flow is selected and that it is possible to overload the patient with fluid.

Verify that the pump head is rotating. (The pump head is located behind the transparent pump door. See Items 2 and 15 in Section 3.1, Controls on the Front of the Pump.)

5.5 Setting the Low (Standby) and High (Ablation) Flow Rates

WARNING
Refer to the instructions for use for the catheter to determine appropriate flow rates for the catheter.

The flow rates can be changed at any time, including when low (standby) flow or high (ablation) flow is active.

Turn the **Low (Standby) Flow** knob to set the low (standby) flow rate (milliliters per minute).

Turn the **High (Ablation) Flow** knob to set the high (ablation) flow rate (milliliters per minute).

Note: When the pump is connected to a SmartAblate™ RF Generator, the generator will impose restrictions on the flow rate that can be set.

5.6 Stopping the Irrigation Flow

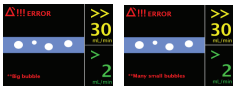
Press the **Stop** button to stop the irrigation flow.

or

Press the **Stand-by** button briefly (less than 3 seconds) to stop the irrigation flow.

Remove the tubing after use.

5.7 Air Bubble Error



When an air bubble is detected in the SmartAblate™ Irrigation Tubing Set in the area of the pump's bubble sensor during high (ablation) or low (standby) flow, the pump sounds an alarm, an error message and images appear on the pump's screen, the **Alarm** indicator light turns on, and the air bubble indicator light changes from green to red (see Section 3.1, Controls on the Front of the Pump).

Immediately turn the 4-way stopcock on the SmartAblate™ Irrigation Tubing Set so that the fluid is not routed to the catheter. Then, press the **Stop**

button to stop the alarm sound. Flush the bubble(s) from the tubing per Section 5.3, Flushing to Eliminate Air in the Tubing and Catheter. After flushing, turn the 4-way stopcock to allow fluid to be routed to the catheter again.

Note: After an air bubble has been detected, the tubing must be flushed. It is not possible to start fluid delivery using the **Low (Standby) Flow**

or **High (Ablation) Flow**

buttons if flushing has not been performed.

5.8 Communication with the SmartAblate™ RF Generator

When the pump is properly connected to the SmartAblate™ RF Generator, this image appears at the bottom of the pump's screen. You can control the pump from the generator when this image is displayed on the pump's screen.

This grayed out image appears at the bottom of the pump's screen when the pump is connected to the generator and you use the pump's user interface to adjust a pump setting. After the generator recognizes the change, the white image shown above reappears.

5.9 Foot Pedal

If a SmartAblate™ System foot pedal is connected to the pump, the foot pedal can be pressed to start the pump in high (ablation) flow mode. This is the same as pressing the **High (Ablation) Flow**

button. When the foot pedal is released, the flow continues at the low (standby) flow rate.

When the foot pedal is properly connected to the pump, this image appears at the bottom of the pump's screen.

6 Troubleshooting

6.1 Warnings

AI = Alarm Indicator (see Item 7 in Section 3.1, Controls on the Front of the Pump)
BI = Bubble Indicator (see Item 16 in Section 3.1, Controls on the Front of the Pump)

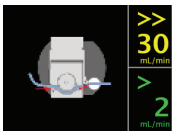
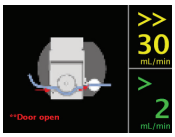
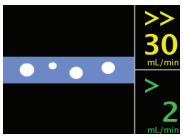
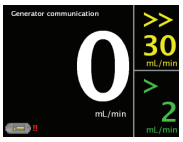
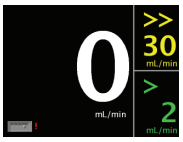
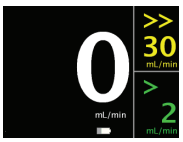
Image	AI	BI	Message	Reason	What To Do
	Off	Off	*none*	The door is open during no flow.	N/A – information only
	On, red	Off	Door open	The door is open during high (ablation), low (standby), or flush flow.	N/A – information only (Opening the door during motor rotation stops the pump.)
	Off	Blinks red	*none*	A bubble was detected during no flow either because there is air in the tubing or because the tubing is not in the bubble sensor.	**!! Patient danger !!** Immediately turn the 4-way stopcock on the SmartAblate™ Irrigation Tubing Set so that the fluid is not routed to the catheter. Be sure to clear the bubble before starting the flow, even if the warning message disappears (see Section 5.3, Flushing to Eliminate Air in the Tubing and Catheter). **Note:** Opening the door can move the tubing slightly, causing the bubbles to move out of the bubble sensor area. Inspect the tubing carefully!
none	Off	Off	Button > stuck?	The **> low (standby) flow** button was pressed for more than 25 seconds or the **>** button is stuck.	Release the **> low (standby) flow** button. If the warning does not disappear, contact Customer Support.
none	Off	Off	Button >> stuck?	The **>> high (ablation) flow** button was pressed for more than 25 seconds or the **>>** button is stuck.	Release the **>> high (ablation) flow** button. If the warning does not disappear, contact Customer Support.
none	Off	Off	Button >>> stuck?	The **>>> flush** flow button was pressed for more than 25 seconds or the **>>>** button is stuck.	Release the **>>> flush** flow button. If the warning does not disappear, contact Customer Support.

Image	AI	BI	Message	Reason	What To Do
none	Off	Off	Button STOP stuck?	The **Stop** button was pressed for more than 25 seconds or the **Stop** button is stuck.	Release the **Stop** button. If the warning does not disappear, contact Customer Support.
none	Off	Off	Button stuck?	The **> low (standby) flow, >> high (ablation) flow**, **>>> flush** flow, or **Stop** button was pressed for more than 25 seconds or one of these buttons is stuck.	Release the pressed button(s). If the warning does not disappear, contact Customer Support.
	Off	Off	Generator commun-ication	Two pumps are connected to the SmartAblate™ RF Generator. or There is a communication problem with the SmartAblate™ RF Generator.	If two pumps are connected, both pumps will go into low (standby) flow. Disconnect one pump from the generator. If only one pump is connected, disconnect the pump connection cable from the generator, reconnect it, and wait 5 seconds. If the warning occurs again, replace the connection cable with a new cable. If the problem persists, operate the pump using the pump user interface and contact Customer Support.
	Off	Off	*none*	There is a problem with the connection cable from the generator to the pump.	Disconnect the cable and reconnect it or turn the pump off and on. If the problem persists, operate the pump using the pump user interface or the foot pedal and contact Customer Support.
	Off	Off	*none*	There is a problem with the foot pedal.	Disconnect the foot pedal and reconnect it or turn the pump off and on. If the problem persists, operate the pump using the pump user interface or the generator interface and contact Customer Support.
	Off	Off	*none*	The internal battery has low voltage.	Contact Customer Support.

6.2 Errors

Each error situation generates an alarm (see Section 7.9, Alarm Specifications).

AI = Alarm Indicator (see Item 7 in Section 3.1, Controls on the Front of the Pump)
BI = Bubble Indicator (see Item 16 in Section 3.1, Controls on the Front of the Pump)

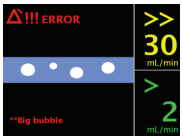
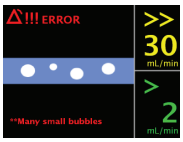
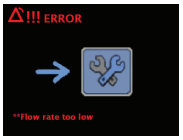
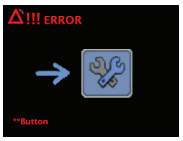
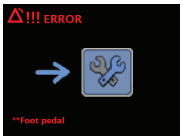
Image	AI	BI	Message	Reason	What To Do
	Blinks red	Blinks red	Big bubble	A big bubble was detected during high (ablation) or low (standby) flow.	**!! Patient danger !!** Immediately turn the 4-way stopcock on the SmartAblate™ Irrigation Tubing Set so that the fluid is not routed to the catheter. Then press the **Stop** button on the pump. Be sure to clear the bubble before starting the flow, even if the error message disappears. (See Section 5.3, Flushing to Eliminate Air in the Tubing and Catheter.) **Note:** Opening the door can move the tubing slightly, causing the bubbles to move out of the bubble sensor area. Inspect the tubing carefully!
	Blinks red	Blinks red	Many small bubbles	Many small bubbles were detected during high (ablation) or low (standby) flow.	**!! Patient danger !!** Immediately turn the 4-way stopcock on the SmartAblate™ Irrigation Tubing Set so that the fluid is not routed to the catheter. Then press the **Stop** button on the pump. Be sure to clear the bubbles before starting the flow, even if the error message disappears. (See Section 5.3, Flushing to Eliminate Air in the Tubing and Catheter.) **Note:** Opening the door can move the tubing slightly, causing the bubbles to move out of the bubble sensor area. Inspect the tubing carefully!

Image	AI	BI	Message	Reason	What To Do
	Blinks red	Off	Flow rate too low	The flow rate is lower than the set rate. Either there is an interruption in the pump head rotation or there is a hardware failure.	Check for an interruption in the pump head rotation, such as a blocked fluid path in the tubing (pinched tubing) or damage to the tubing in the pump head area. If an interruption is found, clear the interruption. If the tubing is damaged, replace the tubing. Then turn the pump off and on. If the error persists, contact Customer Support.
	Blinks red	Off	Button	A button was pressed while the pump was powering on.	Turn the pump off and on. If the error persists, contact Customer Support.
	Blinks red	Off	Foot pedal	The foot pedal was pressed too gently or not in the center or the foot pedal was pressed while the pump was powering on.	Turn the pump off and on, then press the foot pedal again. If the error occurs again, disconnect the foot pedal and connect a different foot pedal or try operating the pump without the foot pedal. If the error persists, contact Customer Support.

6.3 System Errors

Each error situation generates an alarm (see Section 7.9, Alarm Specifications).

AI = Alarm Indicator (see Item 7 in Section 3.1, Controls on the Front of the Pump)
BI = Bubble Indicator (see Item 16 in Section 3.1, Controls on the Front of the Pump)

Image	AI	BI	Message	Reason	What To Do
	Blinks red	Off	varies	There is a system error.	If you see this image with any message that is not listed in Section 6.2, Errors, turn the pump off and on. If the error persists, contact Customer Support.

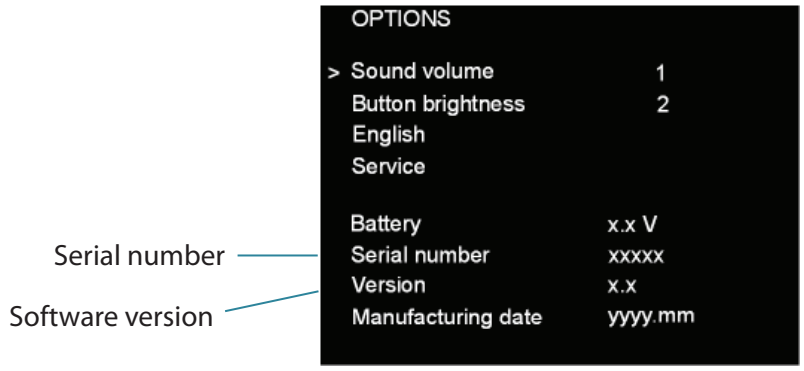
6.4 Other Troubleshooting

Problem	What To Do
The pump will not turn on.	Verify that the power supply meets the specifications in Section 7.1, Specifications, and then check to see whether a fuse is broken. If a fuse is broken, replace it (see Section 3.6, Fuses). If the fuse is not broken or if a new fuse breaks, call Customer Support.
On startup, the SmartAblate™ System logo does not appear, the alarm and air bubble indicators do not light, or there is no audible tone.	Press and hold the **Stand-by** button for approximately 3 seconds to turn off the pump. Then press the **Stand-by** button again to turn the pump back on. If the problem persists, contact Customer Support.
The pump turns on when you don't want it on.	The pump turns on automatically if it is connected to the SmartAblate™ RF Generator and the generator is turned on. Press the **Stand-by** button on the pump to put the pump into sleep mode (see Section 5.1, Turning the Pump On and Off).

6.5 Determining the Pump's Serial Number and Software Version

Customer Support may ask for the pump's serial number and software version.

Options Screen



Turn off the pump and close the pump door.

Press and hold the **Low (Standby) Flow** button while you briefly press the **Stand-by** button. Release the **Low (Standby) Flow** button when the Options screen appears displaying the serial number and software version.

Press the **Stand-by** button to remove the information from the screen. The pump will turn off.

7 Technical Data

7.1 Specifications

Mains

Voltage	100-120 V ± 10% 220-230 V ± 10%
Frequency	50/60 Hz
Power consumption	30 VA

Mode of Operation

Continuous operation

Flow Accuracy (up to 75 psi)

1 mL/min = -20% to +20%
2-5 mL/min = -10% to +20%
6-39 mL/min = -5% to +15%
40-60 mL/min = -10% to +20%
Flush (100 mL/min) = -10% to +20%

Bubble Detection

Designed to detect bubbles ≥ 2 µL

Adjustment of the Flow Rates (in 1 mL/min steps)

Low (Standby) Flow	1 mL/min - 5 mL/min
High (Ablation) Flow	6 mL/min - 30 mL/min (versions US and JP) 6 mL/min - 60 mL/min (version WW)

Maximum Infusion Pressure

115 psi

Sound Pressure Level for Error Messages

45 to 65 dB(A) (measured 1 m from pump)

Fuses

T500 mAH 250V

Other

Classifications	Class I and defibrillation proof type CF (as defined in IEC/EN 60601-1) Class IIa (as defined in MDD 93/42/EEC) Class 3, FDA
Weight	5.5 kg
Dimensions	195 mm wide x 180 mm high x 235 mm long
IP rating	IP54

7.2 Storage and Shipping Conditions

Ambient temperature	-30° to +65°C
Relative humidity	10% to 90% (non-condensing)
Atmospheric pressure	500 to 1060 mbar

7.3 Operating Conditions

Ambient temperature	10° to 40°C
Relative humidity	10% to 90% (non-condensing)
Atmospheric pressure	700 to 1060 mbar

7.4 Safety Inspections

Important Notice

To ensure the safety of the SmartAblate™ Irrigation Pump, repairs and safety inspections may be performed only by the manufacturer, a service engineer certified by the manufacturer, or a service center certified by the manufacturer. The safety inspections must be performed at least once a year and after every repair, according to IEC/EN 60601-1 and its sub-standards and IEC/EN 62353.

7.5 Maintenance

Inspect the pump before each use. Perform the following verifications.

- The **High (Ablation) Flow** and **Low (Standby) Flow** knobs are not loose and the values on the screen change as expected when the knob is turned.
- None of the receptacles is damaged or loose.
- The potential equalization port is not damaged and is not loose.
- The mains cable is not damaged.
- The foot pedal is not damaged.

Once a year, perform the verifications listed above as well as those listed below.

- The device label is present and readable.
- The foot pedal functions correctly when tested with the SmartAblate™ Irrigation Pump.
- The flow rate is accurate. Follow the instructions for use provided with the SmartAblate™ Irrigation Pump Test Kit.

If desired, a service contract can be arranged. Contact Customer Support.

7.6 Repairs

There are no parts in the SmartAblate™ Irrigation Pump that may be serviced by the user. (Exception: The fuses may be replaced per Section 3.6, Fuses). Repairs or any changes to the pump and the accessories must be performed only by the manufacturer, a service engineer authorized by the manufacturer, or service centers certified by the manufacturer.

7.7 Conformance to Standards

The SmartAblate™ Irrigation Pump meets the requirements of the following standards.

Standard	Title
CAN/CSA C22.2 No. 601.1, B-90	Medical electrical equipment - Part 1: General requirements for safety
CMDR	Canadian Medical Devices Regulations
DIN EN 980	Symbols for use in the labeling of medical devices
DIN EN 1041	Information supplied by the manufacturer of medical devices
DIN EN ISO 14971	Medical devices - Application of risk management to medical devices
EU Dir. 2002/96/EC	EU Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE)
EU Dir. 2006/66/EC	Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC
IEC 60812	Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)
IEC/EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC/EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC/EN 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
IEC/EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC/EN 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC/EN 60601-1-9	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

Standard	Title
IEC/EN 62304	Medical device software - Software life cycle processes
IEC/EN 62353	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
IEC/EN 62366	Medical devices - Application of usability engineering to medical devices
MDD 93/42/EEC / MPG (Medical Products Law)	Medical Device Directive (MDD) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety

7.8 EMC Information and Technical Description

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables approved by the manufacturer of the SmartAblate™ Irrigation Pump as replacement parts for internal components, may result in increased emissions or decreased immunity of the SmartAblate™ Irrigation Pump.

Electromagnetic Emissions

The SmartAblate™ Irrigation Pump is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ Irrigation Pump should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The SmartAblate™ Irrigation Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SmartAblate™ Irrigation Pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The SmartAblate™ Irrigation Pump is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ Irrigation Pump should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartAblate™ Irrigation Pump requires continued operation during power mains interruptions, it is recommended that the SmartAblate™ Irrigation Pump be powered from an uninterruptible power supply. Note that a 5 second removal of power, as tested, results in the device shutting down and requires user intervention to restart. There was no interruption of operation for other tests.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level. The SmartAblate™ Irrigation Pump was tested at 100 and 230 VAC.

Electromagnetic Immunity

The SmartAblate™ Irrigation Pump is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ Irrigation Pump should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the SmartAblate™ Irrigation Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartAblate™ Irrigation Pump is used exceeds the applicable RF compliance level above, the SmartAblate™ Irrigation Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SmartAblate™ Irrigation Pump.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the SmartAblate™ Irrigation Pump

The SmartAblate™ Irrigation Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the SmartAblate™ Irrigation Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartAblate™ Irrigation Pump as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

EMC Information and Technical Description

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

⚠ Warning: The use of ACCESSORIES, transducers, and cables other than those specified, with the exception of transducers and cables approved by the manufacturer of the SmartAblate™ Irrigation Pump as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the SmartAblate™ Irrigation Pump.

⚠ Warning: The SmartAblate™ Irrigation Pump may be operated in the immediate vicinity of the SmartAblate™ RF Generator. However, do not operate the pump in the immediate vicinity of devices that are not approved for electromagnetic compatibility (EMC) with the pump. If such operation is unavoidable, regularly monitor the pump to ensure proper functioning.

⚠ Warning: The SmartAblate™ Irrigation Pump may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

The following instructions must be followed to avoid disturbance of the measurement quality:

- The SmartAblate™ Irrigation Pump may be operated only with cables specified by the manufacturer.
- The SmartAblate™ Irrigation Pump must be connected with the grounding cable to a separate grounding point.
- All devices in the patient area that are connected to the SmartAblate™ Irrigation Pump must be on the same mains.
- All devices in the patient area that are connected to the SmartAblate™ Irrigation Pump must be connected to separate ground points with their own grounding cables.

7.9 Alarm Specifications

After an alarm event occurs, there may be a delay of not more than 500 ms before the related sound, light, and/or message are produced.

AI = Alarm Indicator (see Item 7 in Section 3.1, Controls on the Front of the Pump)
BI = Bubble Indicator (see Item 16 in Section 3.1, Controls on the Front of the Pump)

No.	Event	Tone	AI	BI	Reset Action	Comments
1	The **> low (standby) flow, >> high (ablation) flow**, **>>> flush** flow, or **Stop** button was pressed	Pulse pattern: none Tone frequency: 2 kHz ± 20% Tone on: 25 ms	Off	Off	*none*	Information tone
2	The foot pedal was pressed.	Pulse pattern: none Tone frequency: 2 kHz ± 20% Tone on: 25 ms	Off	Off	*none*	Information tone
3	The foot pedal was released.	Pulse pattern: none Tone frequency: 2 kHz ± 20% Tone on: 25 ms	Off	Off	*none*	Information tone
4	High (ablation) flow was started from generator (does not apply to SmartAblate™ RF Generator).	Pulse pattern: none Tone frequency: 2 kHz ± 20% Tone on: 25 ms	Off	Off	*none*	Information tone
5	High (ablation) flow was stopped from generator (does not apply to SmartAblate™ RF Generator).	Pulse pattern: none Tone frequency: 2 kHz ± 20% Tone on: 25 ms	Off	Off	*none*	Information tone

No.	Event	Tone	AI	BI	Reset Action	Comments
6	"Door open" message	Pulse pattern: none Tone frequency: 2 kHz ± 20% Tone on: 25 ms	On, red	Off	Close door.	Information alarm
7	"Big bubble" message	Pulse pattern: ti-ti-ti--ti-ti----------ti-ti-ti--ti-ti Tone frequency: 910 Hz ± 20% Tone pause: 10 s	Blinks red 2Hz, 40% on (± 20%)	Blinks red 2Hz, 40% on (± 20%)	Press **Stop** button.	High priority alarm
8	"Many small bubbles" message	Pulse pattern: ti-ti-ti--ti-ti----------ti-ti-ti--ti-ti Tone frequency: 910 Hz ± 20% Tone pause: 10 s	Blinks red 2Hz, 40% on (± 20%)	Blinks red 2Hz, 40% on (± 20%)	Press **Stop** button.	High priority alarm
9	"Motor direction" message	Pulse pattern: ti-ti-ti--ti-ti----------ti-ti-ti--ti-ti Tone frequency: 910 Hz ± 20% Tone pause: 10 s	Blinks red 2Hz, 40% on (± 20%)	Off	*none*	High priority alarm
10	"Flow not zero" message	Pulse pattern: ti-ti-ti--ti-ti----------ti-ti-ti--ti-ti Tone frequency: 910 Hz ± 20% Tone pause: 10 s	Blinks red 2Hz, 40% on (± 20%)	Off	*none*	High priority alarm
11	Other errors (examples: "Flow rate too low,""Foot pedal,""Motor power supply" messages)	Pulse pattern: ti-ti-ti--ti-ti----------ti-ti-ti--ti-ti Tone frequency: 910 Hz ± 20% Tone pause: 10 s	Blinks red 2Hz, 40% on (± 20%)	Off	*none*	High priority alarm

Note: All alarms are technical alarms.

8 Symbols

Symbol	Description
	SmartAblate™ Irrigation Pump
Distributed by	The device is distributed by
Manufactured by	The device is manufactured by
	Quantity
	Follow operating instructions
	Upper and lower temperature limits (storage and shipping conditions)
	Upper and lower humidity limitation (storage and shipping conditions)
	Upper and lower atmospheric pressure limitation (storage and shipping conditions)
	Keep dry
	All patient connections of the device are defibrillation-proof type CF applied parts
	Lot number
	Catalog number
	Alarm
	Rotational adjustment. Clockwise rotation increases value.
	Flow direction
	Potential equalization port
	Foot pedal receptacle
COMM	Communication connector (to generator, for example)
	Sensor receptacle
	Fuses
	Alternating current

Symbol	Description
	Manufacturer
	Manufacturing date
SN	Serial number
JP	Japanese version of the SmartAblate™ Irrigation Pump
US	United States version of the SmartAblate™ Irrigation Pump
WW	Worldwide version of the SmartAblate™ Irrigation Pump (except the United States, Japan, and China)
	Medical – General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 / CAN/CSA C22.2 NO. 601-1 / ANSI/ AAMI ES60601-1 (2005) / CAN/CSA C22.2 NO. 60601-1 (2008) 40GF
	Caution
	Follow operating instructions
Made in Germany	Certificate of origin in Germany
CE 0366	CE marking with the number of the notified body
	Separate collection for electrical and electronic equipment
	The device does not contain phthalates
	The device is latex-free
	The device may be damaged by electrostatic discharge (ESD) if a person without ESD protection touches a COMM receptacle. Do not touch without appropriate ESD protection.
IP54	The device is protected against dust and is protected against splashing water
HW-Rev.	Hardware revision number

9 Warranty

9.1 Transit Damage

The SmartAblate™ Irrigation Pump and accessories must be examined for transit damage immediately after receipt. If the pump and accessories are damaged, notify Customer Support. Damage claims can be validated only if the seller or the shipping agent is informed immediately. For your convenience, an "Error Report" form is shipped with the pump; you can use this form to record any damage.

9.2 Warranty

The warranty for the SmartAblate™ Irrigation Pump warrants that the pump will conform to its product specifications for a period of one year from the date of shipment or for the period of time defined in the purchase contract. Exceptions to the warranty are accessories, connection cables, and disposable parts. Repairs or any changes may be performed only by the manufacturer, a service engineer authorized by the manufacturer, or a service center authorized by the manufacturer. The warranty is voided if improper modifications or repairs are performed. The warranty is not extended or renewed by services performed under warranty.

9.3 Product Liability

Product liability is assumed by STOCKERT GmbH under the following conditions:

- The pump has been operated only with original STOCKERT GmbH accessories (see Chapter 4, Accessories).
- Repairs to the pump and to the accessories have been performed only by the manufacturer, a service engineer authorized by the manufacturer, or a service center authorized by the manufacturer.

Manufactured By

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

SMARTABLATE™ Irrigation Pump
Firmware 1.XX

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